



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

New York District

Food & Drug Administration  
158-15 Liberty Avenue  
Jamaica, NY 11433

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Frank Russo  
President  
Gloucester Fish Co., Inc.  
96 South Street  
New York, NY 10038

August 8, 2002

Ref: NYK-2002-41

Dear Mr. Russo:

We inspected your firm, located at 96 South Street, New York, New York on June 28, 2002, July 3, 2002 and July 25, 2002, and found that you have serious deviations from the Seafood Hazard Analysis Critical Control Point (HACCP) regulations (Title 21, Code of Federal Regulations, Part 123 (21 CFR 123)), and the Current Good Manufacturing Practice (CGMP) regulations in manufacturing, packing, or holding food for human consumption, (21 CFR 110). These deviations cause your refrigerated ready-to-eat steamed crabmeat to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the Seafood HACCP regulations through the links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations included, but are not limited to, the following:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for refrigerated ready-to-eat steamed crabmeat to control the food safety hazards of pathogen growth and toxin formation during receipt, display and storage.
2. You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor these conditions with sufficient frequency to ensure control as evidenced by monitoring records maintained for these conditions. Review of the sanitation monitoring record for the dates May 10, 2002 to June 28, 2002 revealed all entries were made on a weekly basis although the form entitled "SHELLFISH SANITATION MONITORING" directs that this monitoring be performed daily.

We may take further action if you do not promptly correct these deviations. For instance, we may take action without further notice to seize your products and/or enjoin your firm from operating.

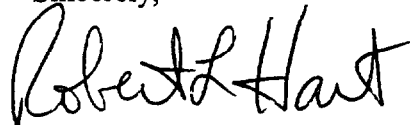
Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

In addition, although your firm does not have a HACCP plan for refrigerated ready-to-eat steamed crabmeat, it was noted that your firm maintains temperature monitoring records for the cooler used for storage of this product. The monitoring record dated May 6, 2002 to June 28, 2002 for this cooler also shows weekly entries of time and temperature although the form directs "daily" monitoring of the cooler. Monitoring of cooler storage must be conducted with sufficient frequency to assure proper temperature maintenance throughout the storage of the product.

This letter and the inspectional observations (Form FDA 483) issued to and discussed with John Gutilla, Manager, at the conclusion of the inspection, may not list all the deviations at your facility. You are responsible for ensuring that your seafood processing facility operates in compliance with the Act, the Seafood HACCP regulations and the CGMP regulations. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Lillian C. Aveta, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issues in this letter, please contact Ms. Aveta at (718) 662-5576.

Sincerely,



Jerome G. Woyshner  
District Director  
New York District

